

SEP | 6 | 1997

CHARLES E. VAN HORN

UNITED STATE PEPARTMENT OF COMMERCE Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Re:

Patent Term Extension

Application for

U.S. Patent No. 4,670,455

#22

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 1300 I Street, N.W. Washington, D.C. 20005-3315

Dear Mr. Van Horn:

This is in response to the letter filed September 10, 1997 in the application for patent term extension of the above-identified patent, electing U.S. Patent No. 4,544,664 for extension due to the regulatory review period of the product DOMITOR®.

Only one patent can be extended under 35 U.S.C. § 156 based upon a single regulatory review period of a product. See 35 U.S.C. § 156(c)(3). Since the '664 patent has been extended based upon the regulatory review period of the product DOMITOR®, the application for patent term extension, filed May 10, 1996 and requesting extension of U.S. Patent No. 4,670,455 based upon said regulatory review period, cannot be granted.

Accordingly, the application for patent term extension for U.S. Patent No. 4,670,455 is dismissed.

A single request for reconsideration of this final determination may be made if filed within <u>one</u> month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are applicable to this time period. See 37 CFR 1.750.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson

Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

cc:

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fishers Lane, Room 15-22 Rockville, MD 20857

RE: DOMITOR®

FDA Docket No.: 96E-0194